IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Art Unit 1796

Application No.	:	10/566,873
Confirmation No.	:	9573
Applicant	:	Rachel Butler et al.
Filed	:	July 3, 2006
Title	:	POROUS MATERIAL AND METHOD OF PRODUCTION THEREOF
Examiner	:	Kara B. Negrelli
Docket No.	:	063511-9001-US00

Electronically filed in the United States Patent Office on November 18, 2010 by Dorothy A. Hauser

DECLARATION OF STEVEN PAUL RANNARD UNDER 37 C.F.R. § 1.132

I, Steven Paul Rannard, hereby declare as follows:

1. I am a Professor of Chemistry at the University of Liverpool (UK). I am also a co-founder and Chief Scientific Officer of Iota Nanosolutions. I received a B.Sc. (Hons) degree in Chemistry and Materials Science from the University of Sussex in 1988, and a D.Phil Degree in Polymer Science from the University of Sussex in 1994.

2. I have read the above-identified patent application ("the Application"). A number of the Examples described in the Application were repeated under my supervision, to demonstrate the dissolution properties of said Examples, namely the time taken for the materials made to substantially fully dissolve (as determined by the human eye) in water at 20 °C. The experimental method used to produce the materials is as follows, which is based on that described in the Application.

3. All supercritical fluid emulsifications were conducted in a 10 ml volume, steel pressure vessel, fitted with a pressure transducer, a thermocouple and a 20 mm solid sapphire viewing port. All emulsions were formed in the same manner.

4. Briefly, the reactor vessel was charged with 2 ml of an aqueous solution of the excipients, and a 20 mm cross shaped PTFE stir bar added. The reactor was sealed and filled with CO_2 to a pressure of 1000 psi (+/- 50 psi), at ambient temperature (approximately 20 °C). The two phases were stirred at 500 rpm for 45 minutes, resulting in a uniform, opaque white emulsion. The entire pressure vessel was then cooled via immersion in dry ice until the internal temperature was below -40 °C. The reactor was

then vented to remove the pressurised CO_2 and the solid aqueous phase was freeze dried at a pressure of 40 microbar over a -105 °C condenser for 3 days.

5. The dissolution rates of the resulting dry powders were compared against monolithic ice-templated materials that were prepared by freezing the aqueous solutions of excipients using dry ice and then freeze-drying under the same conditions as for the emulsion-templated material. The dissolution rate was determined by addition of 50 mg of the freeze-dried samples to a 100 ml vessel containing 50 ml of deionised water at ambient temperature (approximately 20 °C), stirred at 400 rpm using a 25 mm cylindrical PTFE stir bar. Dissolution was determined by visual observation.

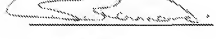
6. The results for the examples prepared are listed in Table 1 below.

Table 1. Dissolution rates for various examples prepared through emulsion- and ice-templating.

Example No.	Mass polymer (mg)	Mass surfactant (mg)	Other (mg)	CO_2 / H_2O (v/v)	Dissolution time (sec)
2	280 dextran	-	-	0 / 100	143
3	280 dextran	40 CTAB	-	0 / 100	107
7	280 dextran	40 CTAB	-	80 / 20	39
15	280 dextran	40 CTAB	20 paracetamol	80 / 20	53

7. Based purely on visual observation, it can clearly be seen that the emulsion-templated materials of Examples 7 and 15 fully dissolve (or at least substantially so, as determined by the human eye) more rapidly (in just 39 seconds and 53 seconds respectively) than the corresponding ice-templated (i.e. without use of CO_2) equivalents of Examples 2 and 3, which take 143 seconds (over 2 minutes) and 107 seconds (almost 2 minutes) to fully dissolve respectively.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issued thereon.



Steven Paul Rannard

16th November 2010

Date